DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95135d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-06

November 5, 2004

Ramzi Abulhaj
President
VitalCare Group, Inc.
8935 NW 27th Street
Miami, Florida 33172

Dear Mr. Abulhaj:

On June 15-17 and 21, 2004, investigators from the Food and Drug Administration (FDA) inspected your establishment, which manufactures sterile irrigation trays, pediatric urine collectors (PUC), bulb syringes, safety lancets, and vaginal specula. These products are medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The inspection revealed that these products are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements set forth in FDA's Quality System (QS) Regulation, codified in Title 21, Code of Federal Regulations (CFR), part 820. In addition, the inspection revealed that your firm failed to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17.

Quality System

The investigators noted the following QS Regulation violations, which are also listed in the Form FDA 483 provided to your facility at the end of the inspection:

1. Failure to conduct quality audits as required by 21 CFR 820.22. Specifically, your firm's Director of Quality Assurance and Quality Control Technician are responsible for performing all internal audits, including audits of matters for which they have direct responsibility. (Form FDA 483, Observation 2.)

2. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a). Specifically, your firm was aware of nonconformities

relating to Sterile Irrigation Trays with Thumb Control Syringes (lot #s [redacted] and [redacted] (seal integrity defects); Sterile Pediatric Urine Collectors (lot #[redacted] (package leak test failures); syringes (product #[redacted] (bulb separation from the barrel); McKesson Pediatric Urine Collectors (lot #s [redacted] and [redacted] 21G Safety Lancets from Resource Services (cracked protective shields and plastic flash anomalies); Vaginal Specula (lot #[redacted] (breakage and failure to meet flash and assembly cleanliness requirements). There is no documentation (MRB or Corrective Action Request) available of the investigation or verification of corrective actions having been taken. Moreover, no risk analysis was conducted after parts or components were changed to ensure the changes were implemented and verified to be effective. (Form FDA 483, Observations Items 3-5.)

3. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). Specifically, you had records indicating that nonconforming product had been returned, but no records of any investigation resulting in the acceptance or rejection of the returned goods or the disposal of these products. (Form FDA 483, Observation 6.)

4. Failure to establish and maintain procedures to ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed, as required by 21 CFR 820.160(a). Specifically, your firm's warehouse is not environmentally controlled and your storage SOP does not include requirements to evaluate product prior to distribution for those devices stored for prolonged periods of time. Some current inventory includes devices that has been stored for several years, e.g., 70 cases of Suction Catheters (lot #[redacted] received in March 2001, 81 cases of IV Pole Kits (lot #[redacted] received in January 2001, and 54 cases of Suction Catheters (lot #[redacted] received on September 2001. (Form FDA 483, Observation 7.)

5. Failure to review, evaluate, and investigate a complaint involving the possible failure of a device, labeling, or packaging to meet its specifications, as required by 21 CFR 820.198(c). Specifically, complaints PCR 13 and PCR 8, involving the failure of vaginal specula to close for removal, resulting in "great discomfort to the patient," were not investigated. (Form FDA 483, Observation 10). Complaints relating to Irrigation Tray Thumb Control Syringes, McKesson brand Pediatric Urine Collectors, and CB Fleet Enema Bags also were not investigated. (Form FDA 483, Observation 8.)

6. Failure to establish and maintain procedures to ensure that DHRs for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance the DMR and the requirements of Part

820, including acceptance records demonstrating the device is manufactured in accordance with the DMR, as required by 21 CFR 820.184(d). Specifically, receiving inspection records could not be located for Sterile Irrigation Tray Thumb Control Syringes, lot [redacted] and for vaginal specula, lot [redacted] Moreover, the Inspection Procedure, IP 125, for Pediatric Urine Collectors does not include a requirement to perform seal integrity testing. Testing is reportedly being done for each lot but not documented. (Form FDA 483, Observation 12.)

7. Failure to document disposition of nonconforming product, as required by 21 CFR 820.90(b)(1). Specifically, Sterile Pediatric Urine Collector, lot [redacted] was returned for package integrity defects, but you failed to document that the lot was destroyed. (Form FDA 483, Observation 13).

8. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit which ensure that oral complaints are documented upon receipt, as required by 21 CFR 820.198(a)(2). Specifically, your firm failed to document an oral complaint received in approximately June 2003 concerning safety lancets. (Form FDA 483, Observation 14.)

Medical Device Reporting (MDR)

9. Failure of your firm's written MDR procedures to include a standardized review process/procedure for determining when an event meets the criteria for reporting under Part 803 of FDA's regulations (21 CFR Part 803). (Form FDA 483, Observation 15.)

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and FDA regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of any steps that you are taking to correct the noted violations, including (1)

the time frames within which the corrections will be completed, (2) any documentation indicating that corrections have been completed, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. We have reviewed your firm's response, signed by Michael McAvenia, Director Quality/Regulatory, dated June 30, 2004, and find that the response is inadequate because it only promises to make the necessary corrective actions. Also for new or updated procedures, there was no evidence that these documents have been implemented and are effective. Your response has been made part of the Florida District file.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

for Elizabeth W. Orr

Emma Singleton
Director, Florida District